

# EXHIBIT Z

# GUIDELINE FOR PREVENTION OF SURGICAL SITE INFECTION, 1999

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The Hospital Infection Control Practices Advisory Committee

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## Special Report

# Guideline for Prevention of Surgical Site Infection, 1999

Alicia J. Mangram, MD; Teresa C. Horan, MPH, CIC; Michele L. Pearson, MD; Leah Christine Silver, BS; William R. Jarvis, MD;  
The Hospital Infection Control Practices Advisory Committee

### EXECUTIVE SUMMARY

The "Guideline for Prevention of Surgical Site Infection, 1999" presents the Centers for Disease Control and Prevention (CDC)'s recommendations for the prevention of surgical site infections (SSIs), formerly called surgical wound infections. This two-part guideline updates and replaces previous guidelines.<sup>1,2</sup>

Part I, "Surgical Site Infection: An Overview," describes the epidemiology, definitions, microbiology, pathogenesis, and surveillance of SSIs. Included is a detailed discussion of the pre-, intra-, and postoperative issues relevant to SSI genesis.

Part II, "Recommendations for Prevention of Surgical Site Infection," represents the consensus of the Hospital Infection Control Practices Advisory Committee (HICPAC) regarding strategies for the prevention of SSIs.<sup>3</sup> Whenever possible, the recommendations in Part II are based on data from well-designed scientific studies. However, there are a limited number of studies that clearly validate risk factors and prevention measures for SSI. By necessity, available studies have often been conducted in narrowly defined patient populations or for specific kinds of operations, making generalization of their findings to all specialties and types of operations potentially problematic. This is especially true regarding the implementation of SSI prevention measures. Finally, some of the infection control practices routinely used by surgical teams cannot be rigorously studied for ethical or logistical reasons (e.g., wearing vs not wearing gloves). Thus, some of the recommendations in Part II are based on a strong theoretical rationale and suggestive evidence in the absence of confirmatory scientific knowledge.

It has been estimated that approximately 75% of all operations in the United States will be performed in "ambulatory," "same-day," or "outpatient" operating rooms by the turn of the century.<sup>4</sup> In recommending various SSI prevention methods, this document makes no distinction between surgical care delivered in such settings and that provided in conventional inpatient operating rooms. This document is primarily intended for use by surgeons, operating room nurses, postoperative inpatient and clinic nurses, infection control professionals, anesthesiologists, healthcare epidemiologists, and other personnel directly responsible for the prevention of nosocomial infections.

This document does *not*:

- Specifically address issues unique to burns, trauma, transplant procedures, or transmission of bloodborne pathogens from healthcare worker to patient, nor does it specifically address details of SSI prevention in pediatric surgical practice. It has been recently shown in a multicenter study of pediatric surgical patients that characteristics related to the operations are more important than those related to the physiologic status of the patients.<sup>5</sup> In general, all SSI prevention measures effective in adult surgical care are indicated in pediatric surgical care.

- Specifically address procedures performed outside of the operating room (e.g., endoscopic procedures), nor does it provide guidance for infection prevention for invasive procedures such as cardiac catheterization or interventional radiology. Nonetheless, it is likely that many SSI prevention strategies also could be applied or adapted to reduce infectious complications associated with these procedures.

- Specifically recommend SSI prevention methods

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*The "Guideline for Prevention of Surgical Site Infection, 1999" is available online at [www.cdc.gov/ncidod/hip](http://www.cdc.gov/ncidod/hip).*

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unique to minimally invasive operations (i.e., laparoscopic surgery). Available SSI surveillance data indicate that laparoscopic operations generally have a lower or comparable SSI risk when contrasted to open operations.<sup>6-11</sup> SSI prevention measures applicable in open operations (e.g., open cholecystectomy) are indicated for their laparoscopic counterparts (e.g., laparoscopic cholecystectomy).

- Recommend specific antiseptic agents for patient preoperative skin preparations or for healthcare worker hand/forearm antisepsis. Hospitals should choose from products recommended for these activities in the latest Food and Drug Administration (FDA) monograph.<sup>12</sup>

## I. SURGICAL SITE INFECTION (SSI): AN OVERVIEW

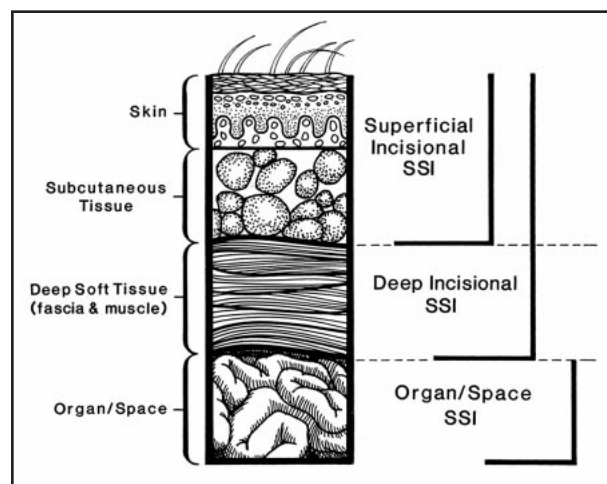
### A. INTRODUCTION

Before the mid-19th century, surgical patients commonly developed postoperative “irritative fever,” followed by purulent drainage from their incisions, overwhelming sepsis, and often death. It was not until the late 1860s, after Joseph Lister introduced the principles of antisepsis, that postoperative infectious morbidity decreased substantially. Lister’s work radically changed surgery from an activity associated with infection and death to a discipline that could eliminate suffering and prolong life.

Currently, in the United States alone, an estimated 27 million surgical procedures are performed each year.<sup>13</sup> The CDC’s National Nosocomial Infections Surveillance (NNIS) system, established in 1970, monitors reported trends in nosocomial infections in U.S. acute-care hospitals. Based on NNIS system reports, SSIs are the third most frequently reported nosocomial infection, accounting for 14% to 16% of all nosocomial infections among hospitalized patients.<sup>14</sup> During 1986 to 1996, hospitals conducting SSI surveillance in the NNIS system reported 15,523 SSIs following 593,344 operations (CDC, unpublished data). Among surgical patients, SSIs were the most common nosocomial infection, accounting for 38% of all such infections. Of these SSIs, two thirds were confined to the incision, and one third involved organs or spaces accessed during the operation. When surgical patients with nosocomial SSI died, 77% of the deaths were reported to be related to the infection, and the majority (93%) were serious infections involving organs or spaces accessed during the operation.

In 1980, Cruse estimated that an SSI increased a patient’s hospital stay by approximately 10 days and cost an additional \$2,000.<sup>15,16</sup> A 1992 analysis showed that each SSI resulted in 7.3 additional postoperative hospital days, adding \$3,152 in extra charges.<sup>17</sup> Other studies corroborate that increased length of hospital stay and cost are associated with SSIs.<sup>18,19</sup> Deep SSIs involving organs or spaces, as compared to SSIs confined to the incision, are associated with even greater increases in hospital stays and costs.<sup>20,21</sup>

Advances in infection control practices include improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis. Despite these activities, SSIs remain a



**FIGURE.** Cross-section of abdominal wall depicting CDC classifications of surgical site infection.<sup>22</sup>

substantial cause of morbidity and mortality among hospitalized patients. This may be partially explained by the emergence of antimicrobial-resistant pathogens and the increased numbers of surgical patients who are elderly and/or have a wide variety of chronic, debilitating, or immunocompromising underlying diseases. There also are increased numbers of prosthetic implant and organ transplant operations performed. Thus, to reduce the risk of SSI, a systematic but realistic approach must be applied with the awareness that this risk is influenced by characteristics of the patient, operation, personnel, and hospital.

### B. KEY TERMS USED IN THE GUIDELINE

#### 1. Criteria for Defining SSIs

The identification of SSI involves interpretation of clinical and laboratory findings, and it is crucial that a surveillance program use definitions that are consistent and standardized; otherwise, inaccurate or uninterpretable SSI rates will be computed and reported. The CDC’s NNIS system has developed standardized surveillance criteria for defining SSIs (Table 1).<sup>22</sup> By these criteria, SSIs are classified as being either incisional or organ/space. Incisional SSIs are further divided into those involving only skin and subcutaneous tissue (superficial incisional SSI) and those involving deeper soft tissues of the incision (deep incisional SSI). Organ/space SSIs involve any part of the anatomy (e.g., organ or space) other than incised body wall layers, that was opened or manipulated during an operation (Figure). Table 2 lists site-specific classifications used to differentiate organ/space SSIs. For example, in a patient who had an appendectomy and subsequently developed an intra-abdominal abscess not draining through the incision, the infection would be reported as an organ/space SSI at the intra-abdominal site. Failure to use objective criteria to define SSIs has been shown to substantially affect reported SSI rates.<sup>23,24</sup> The CDC NNIS definitions of SSIs have been applied consistently by surveillance and surgical personnel in many settings and currently are a de facto national standard.<sup>22,25</sup>

TABLE 1

CRITERIA FOR DEFINING A SURGICAL SITE INFECTION (SSI)\*

**Superficial Incisional SSI**

Infection occurs within 30 days after the operation

*and*

infection involves only skin or subcutaneous tissue of the incision

*and* at least *one* of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat *and* superficial incision is deliberately opened by surgeon, *unless* incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do *not* report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Infection of an episiotomy or newborn circumcision site.
3. Infected burn wound.
4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

*Note:* Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.<sup>4,33</sup>**Deep Incisional SSI**Infection occurs within 30 days after the operation if no implant<sup>†</sup> is left in place or within 1 year if implant is in place and the infection appears to be related to the operation*and*

infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision

*and* at least *one* of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38°C), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

*Notes:*

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.
2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

**Organ/Space SSI**Infection occurs within 30 days after the operation if no implant<sup>†</sup> is left in place or within 1 year if implant is in place and the infection appears to be related to the operation*and*

infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation

*and* at least *one* of the following:

1. Purulent drainage from a drain that is placed through a stab wound<sup>‡</sup> into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

\* Horan TC et al.<sup>22</sup><sup>†</sup> National Nosocomial Infection Surveillance definition: a nonhuman-derived implantable foreign body (e.g., prosthetic heart valve, nonhuman vascular graft, mechanical heart, or hip prosthesis) that is permanently placed in a patient during surgery.<sup>‡</sup> If the area around a stab wound becomes infected, it is not an SSI. It is considered a skin or soft tissue infection, depending on its depth.**2. Operating Suite**

A physically separate area that comprises operating rooms and their interconnecting hallways and ancillary work areas such as scrub sink rooms. No distinction is made between operating suites located in conventional inpatient hospitals and those used for "same-day" sur-

gical care, whether in a hospital or a free-standing facility.

**3. Operating Room**

A room in an operating suite where operations are performed.

#### 4. Surgical Personnel

Any healthcare worker who provides care to surgical patients during the pre-, intra-, or postoperative periods.

#### 5. Surgical Team Member

Any healthcare worker in an operating room during the operation who has a surgical care role. Members of the surgical team may be “scrubbed” or not; scrubbed members have direct contact with the sterile operating field or sterile instruments or supplies used in the field (refer to “Preoperative Hand/Forearm Antisepsis” section).

### C. MICROBIOLOGY

According to data from the NNIS system, the distribution of pathogens isolated from SSIs has not changed markedly during the last decade (Table 3).<sup>26,27</sup> *Staphylococcus aureus*, coagulase-negative staphylococci, *Enterococcus* spp., and *Escherichia coli* remain the most frequently isolated pathogens. An increasing proportion of SSIs are caused by antimicrobial-resistant pathogens, such as methicillin-resistant *S. aureus* (MRSA),<sup>28,29</sup> or by *Candida albicans*.<sup>30</sup> From 1991 to 1995, the incidence of fungal SSIs among patients at NNIS hospitals increased from 0.1 to 0.3 per 1,000 discharges.<sup>30</sup> The increased proportion of SSIs caused by resistant pathogens and *Candida* spp. may reflect increasing numbers of severely ill and immunocompromised surgical patients and the impact of widespread use of broad-spectrum antimicrobial agents.

Outbreaks or clusters of SSIs have also been caused by unusual pathogens, such as *Rhizopus oryzae*, *Clostridium perfringens*, *Rhodococcus bronchialis*, *Nocardia farcinica*, *Legionella pneumophila* and *Legionella dumoffii*, and *Pseudomonas multivorans*. These rare outbreaks have been traced to contaminated adhesive dressings,<sup>31</sup> elastic bandages,<sup>32</sup> colonized surgical personnel,<sup>33,34</sup> tap water,<sup>35</sup> or contaminated disinfectant solutions.<sup>36</sup> When a cluster of SSIs involves an unusual organism, a formal epidemiologic investigation should be conducted.

### D. PATHOGENESIS

Microbial contamination of the surgical site is a necessary precursor of SSI. The risk of SSI can be conceptualized according to the following relationship<sup>37,38</sup>:

$$\frac{\text{Dose of bacterial contamination} \times \text{virulence}}{\text{Resistance of the host patient}} = \text{Risk of surgical site infection}$$

Quantitatively, it has been shown that if a surgical site is contaminated with  $>10^5$  microorganisms per gram of tissue, the risk of SSI is markedly increased.<sup>39</sup> However, the dose of contaminating microorganisms required to produce infection may be much lower when foreign material is present at the site (i.e., 100 staphylococci per gram of tissue introduced on silk sutures).<sup>40-42</sup>

Microorganisms may contain or produce toxins and other substances that increase their ability to invade a host, produce damage within the host, or survive on or in host tissue. For example, many gram-negative bacteria produce

**TABLE 2**

SITE-SPECIFIC CLASSIFICATIONS OF ORGAN/SPACE SURGICAL SITE INFECTION\*

Arterial or venous infection
Breast abscess or mastitis
Disc space
Ear, mastoid
Endocarditis
Endometritis
Eye, other than conjunctivitis
Gastrointestinal tract
Intra-abdominal, not specified elsewhere
Intracranial, brain abscess or dura
Joint or bursa
Mediastinitis
Meningitis or ventriculitis
Myocarditis or pericarditis
Oral cavity (mouth, tongue, or gums)
Osteomyelitis
Other infections of the lower respiratory tract (e.g., abscess or empyema)
Other male or female reproductive tract
Sinusitis
Spinal abscess without meningitis
Upper respiratory tract
Vaginal cuff

\* Horan TC et al.<sup>22</sup>

endotoxin, which stimulates cytokine production. In turn, cytokines can trigger the systemic inflammatory response syndrome that sometimes leads to multiple system organ failure.<sup>43-45</sup> One of the most common causes of multiple system organ failure in modern surgical care is intra-abdominal infection.<sup>46,47</sup> Some bacterial surface components, notably polysaccharide capsules, inhibit phagocytosis,<sup>48</sup> a critical and early host defense response to microbial contamination. Certain strains of clostridia and streptococci produce potent exotoxins that disrupt cell membranes or alter cellular metabolism.<sup>49</sup> A variety of microorganisms, including gram-positive bacteria such as coagulase-negative staphylococci, produce glycocalyx and an associated component called “slime,”<sup>50-55</sup> which physically shields bacteria from phagocytes or inhibits the binding or penetration of antimicrobial agents.<sup>56</sup> Although these and other virulence factors are well defined, their mechanistic relationship to SSI development has not been fully determined.

For most SSIs, the source of pathogens is the endogenous flora of the patient’s skin, mucous membranes, or hollow viscera.<sup>57</sup> When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora.<sup>58</sup> These organisms are usually aerobic gram-positive cocci (e.g., staphylococci), but may include fecal flora (e.g., anaerobic bacteria and gram-negative aerobes) when incisions are made near the perineum or groin. When a gastrointestinal organ is opened

TABLE 3

DISTRIBUTION OF PATHOGENS ISOLATED\* FROM SURGICAL SITE INFECTIONS, NATIONAL NOSOCOMIAL INFECTIONS SURVEILLANCE SYSTEM, 1986 TO 1996

Pathogen	Percentage of Isolates	
	1986-1989 <sup>179</sup> (N=16,727)	1990-1996 <sup>26</sup> (N=17,671)
<i>Staphylococcus aureus</i>	17	20
Coagulase-negative staphylococci	12	14
<i>Enterococcus</i> spp.	13	12
<i>Escherichia coli</i>	10	8
<i>Pseudomonas aeruginosa</i>	8	8
<i>Enterobacter</i> spp.	8	7
<i>Proteus mirabilis</i>	4	3
<i>Klebsiella pneumoniae</i>	3	3
Other <i>Streptococcus</i> spp.	3	3
<i>Candida albicans</i>	2	3
Group D streptococci (non-enterococci)	—	2
Other gram-positive aerobes	—	2
<i>Bacteroides fragilis</i>	—	2

\*Pathogens representing less than 2% of isolates are excluded.

during an operation and is the source of pathogens, gram-negative bacilli (e.g., *E. coli*), gram-positive organisms (e.g., enterococci), and sometimes anaerobes (e.g., *Bacillus fragilis*) are the typical SSI isolates. Table 4 lists operations and the likely SSI pathogens associated with them. Seeding of the operative site from a distant focus of infection can be another source of SSI pathogens,<sup>59-68</sup> particularly in patients who have a prosthesis or other implant placed during the operation. Such devices provide a nidus for attachment of the organism.<sup>50,69-73</sup>

Exogenous sources of SSI pathogens include surgical personnel (especially members of the surgical team),<sup>74-78</sup> the operating room environment (including air), and all tools, instruments, and materials brought to the sterile field during an operation (refer to "Intraoperative Issues" section). Exogenous flora are primarily aerobes, especially gram-positive organisms (e.g., staphylococci and streptococci). Fungi from endogenous and exogenous sources rarely cause SSIs, and their pathogenesis is not well understood.<sup>79</sup>

## E. RISK AND PREVENTION

The term *risk factor* has a particular meaning in epidemiology and, in the context of SSI pathophysiology and prevention, strictly refers to a variable that has a significant, independent association with the development of SSI after a specific operation. Risk factors are identified by multivariate analyses in epidemiologic studies. Unfortunately, the term risk factor often is used in the surgical literature in a broad sense to include patient or operation features which, although associated with SSI development in univariate analysis, are not necessarily independent predictors.<sup>80</sup> The literature cited in the sections that follow

includes risk factors identified by both univariate and multivariate analyses.

Table 5 lists patient and operation characteristics that may influence the risk of SSI development. These characteristics are useful in two ways: (1) they allow stratification of operations, making surveillance data more comprehensible; and, (2) knowledge of risk factors before certain operations may allow for targeted prevention measures. For example, if it is known that a patient has a remote site infection, the surgical team may reduce SSI risk by scheduling an operation after the infection has resolved.

An SSI prevention measure can be defined as an action or set of actions intentionally taken to reduce the risk of an SSI. Many such techniques are directed at reducing opportunities for microbial contamination of the patient's tissues or sterile surgical instruments; others are adjunctive, such as using antimicrobial prophylaxis or avoiding unnecessary traumatic tissue dissection. Optimum application of SSI prevention measures requires that a variety of patient and operation characteristics be carefully considered.

## 1. Patient Characteristics

In certain kinds of operations, patient characteristics possibly associated with an increased risk of an SSI include coincident remote site infections<sup>59-68</sup> or colonization,<sup>81-83</sup> diabetes,<sup>84-87</sup> cigarette smoking,<sup>85,88-92</sup> systemic steroid use,<sup>84,87,93</sup> obesity (>20% ideal body weight),<sup>85-87,94-97</sup> extremes of age,<sup>92,98-102</sup> poor nutritional status,<sup>85,94,98,103-105</sup> and perioperative transfusion of certain blood products.<sup>106-109</sup>

### a. Diabetes

The contribution of diabetes to SSI risk is controversial,<sup>84-86,98,110</sup> because the independent contribution of diabetes to SSI risk has not typically been assessed after controlling for potential confounding factors. Recent preliminary findings from a study of patients who underwent coronary artery bypass graft showed a significant relationship between increasing levels of HgA1c and SSI rates.<sup>111</sup> Also, increased glucose levels (>200 mg/dL) in the immediate postoperative period (≤48 hours) were associated with increased SSI risk.<sup>112,113</sup> More studies are needed to assess the efficacy of perioperative blood glucose control as a prevention measure.

### b. Nicotine use

Nicotine use delays primary wound healing and may increase the risk of SSI.<sup>85</sup> In a large prospective study, current cigarette smoking was an independent risk factor for sternal and/or mediastinal SSI following cardiac surgery.<sup>85</sup> Other studies have corroborated cigarette smoking as an important SSI risk factor.<sup>88-92</sup> The limitation of these studies, however, is that terms like *current cigarette smoking* and *active smokers* are not always defined. To appropriately determine the contribution of tobacco use to SSI risk, standardized definitions of smoking history must be adopted and used in studies designed to control for confounding variables.

### c. Steroid use

Patients who are receiving steroids or other immuno-

TABLE 4

OPERATIONS, LIKELY SURGICAL SITE INFECTION (SSI) PATHOGENS, AND REFERENCES ON USE OF ANTIMICROBIAL PROPHYLAXIS\*

Operations	Likely Pathogens†‡	References
Placement of all grafts, prostheses, or implants	<i>Staphylococcus aureus</i> ; coagulase-negative staphylococci	269,282-284,290
Cardiac	<i>S. aureus</i> ; coagulase-negative staphylococci	251-253,462,463
Neurosurgery	<i>S. aureus</i> ; coagulase-negative staphylococci	241,249,258,259,261,464,465
Breast	<i>S. aureus</i> ; coagulase-negative staphylococci	242,248
Ophthalmic	<i>S. aureus</i> ; coagulase-negative staphylococci; streptococci; gram-negative bacilli	466
Limited data; however, commonly used in procedures such as anterior segment resection, vitrectomy, and scleral buckles		
Orthopedic	<i>S. aureus</i> ; coagulase-negative staphylococci; gram-negative bacilli	60,243-246,254,255,467-473
Total joint replacement		
Closed fractures/use of nails, bone plates, other internal fixation devices		
Functional repair without implant/device		
Trauma		
Noncardiac thoracic	<i>S. aureus</i> ; coagulase-negative staphylococci;	240,247,474,475
Thoracic (lobectomy, pneumonectomy, wedge resection, other noncardiac mediastinal procedures)	<i>Streptococcus pneumoniae</i> ; gram-negative bacilli	
Closed tube thoracostomy		
Vascular	<i>S. aureus</i> ; coagulase-negative staphylococci	250,463,476,477
Appendectomy	Gram-negative bacilli; anaerobes	263,452,478
Biliary tract	Gram-negative bacilli; anaerobes	260,262,479-484
Colorectal	Gram-negative bacilli; anaerobes	200,239,256,287-289,485-490
Gastroduodenal	Gram-negative bacilli; streptococci; oropharyngeal anaerobes (e.g., peptostreptococci)	256,257,491-493
Head and neck (major procedures with incision through oropharyngeal mucosa)	<i>S. aureus</i> ; streptococci; oropharyngeal anaerobes (e.g., peptostreptococci)	494-497
Obstetric and gynecologic	Gram-negative bacilli; enterococci; group B streptococci; anaerobes	270-280,435
Urologic	Gram-negative bacilli	267
May not be beneficial if urine is sterile		

\* Refer to "Antimicrobial prophylaxis in surgery," *The Medical Letter*, 1997,<sup>266</sup> for current recommendations of antimicrobial agents and doses.

† Likely pathogens from both endogenous and exogenous sources.

‡ Staphylococci will be associated with SSI following all types of operations.

suppressive drugs preoperatively may be predisposed to developing SSI,<sup>84,87</sup> but the data supporting this relationship are contradictory. In a study of long-term steroid use in patients with Crohn's disease, SSI developed significantly more often in patients receiving preoperative steroids (12.5%) than in patients without steroid use (6.7%).<sup>93</sup> In contrast, other investigations have not found a relationship between steroid use and SSI risk.<sup>98,114,115</sup>

#### d. Malnutrition

For some types of operations, severe protein-calorie malnutrition is crudely associated with postoperative nosocomial infections, impaired wound healing dynamics, or death.<sup>116-124</sup> The National Academy of Sciences/National Research Council (NAS/NRC),<sup>94</sup> Study on the Efficacy of Infection Control (SENIC),<sup>125</sup> and NNIS<sup>126</sup> schemes for SSI risk stratification do not explicitly incorporate nutritional status as a predictor variable, although it may be represented indirectly in the latter two. In a widely quoted 1987

study of 404 high-risk general surgery operations, Christou and coworkers derived an SSI probability index in which final predictor variables were patient age, operation duration, serum albumin level, delayed hypersensitivity test score, and intrinsic wound contamination level.<sup>117</sup> Although this index predicted SSI risk satisfactorily for 404 subsequent patients and was generally received as a significant advance in SSI risk stratification, it is not widely used in SSI surveillance data analysis, surgical infection research, or analytic epidemiology.

Theoretical arguments can be made for a belief that severe preoperative malnutrition should increase the risk of both incisional and organ/space SSI. However, an epidemiologic association between incisional SSI and malnutrition is difficult to demonstrate consistently for all surgical subspecialties.<sup>118-120,124,127-131</sup> Multivariate logistic regression modeling has shown that preoperative protein-calorie malnutrition is not an independent predictor of

**TABLE 5**  
PATIENT AND OPERATION CHARACTERISTICS THAT MAY INFLUENCE  
THE RISK OF SURGICAL SITE INFECTION DEVELOPMENT

Patient
Age
Nutritional status
Diabetes
Smoking
Obesity
Coexistent infections at a remote body site
Colonization with microorganisms
Altered immune response
Length of preoperative stay
Operation
Duration of surgical scrub
Skin antisepsis
Preoperative shaving
Preoperative skin prep
Duration of operation
Antimicrobial prophylaxis
Operating room ventilation
Inadequate sterilization of instruments
Foreign material in the surgical site
Surgical drains
Surgical technique
Poor hemostasis
Failure to obliterate dead space
Tissue trauma

Adapted from references 25, 37.

mediastinitis after cardiac bypass operations.<sup>85,132</sup>

In the modern era, total parenteral nutrition (TPN) and total enteral alimentation (TEA) have enthusiastic acceptance by surgeons and critical care specialists.<sup>118,133-137</sup> However, the benefits of preoperative nutritional repletion of malnourished patients in reducing SSI risk are unproven. In two randomized clinical trials, preoperative "nutritional therapy" did not reduce incisional and organ/space SSI risk.<sup>138-141</sup> In a recent study of high-risk pancreatectomy patients with cancer, the provision of TPN preoperatively had no beneficial effect on SSI risk.<sup>142</sup> A randomized prospective trial involving 395 general and thoracic surgery patients compared outcomes for malnourished patients preoperatively receiving either a 7- to 15-day TPN regimen or a regular preoperative hospital diet. All patients were followed for 90 days postoperatively. There was no detectable benefit of TPN administration on the incidence of incisional or organ/space SSI.<sup>143</sup> Administering TPN or TEA may be indicated in a number of circumstances, but such repletion cannot be viewed narrowly as a prevention measure for organ/space or incisional SSI risk. When a major elective operation is necessary in a severely malnourished patient, experienced surgeons often use both pre- and postoperative nutritional support in consideration of the major morbidity associated with numerous potential

complications, only one of which is organ/space SSI.<sup>118,124,130,133,137,138,144-149</sup> In addition, postoperative nutritional support is important for certain major oncologic operations,<sup>135,136</sup> after many operations on major trauma victims,<sup>134</sup> or in patients suffering a variety of catastrophic surgical complications that preclude eating or that trigger a hypermetabolic state. Randomized clinical trials will be necessary to determine if nutritional support alters SSI risk in specific patient-operation combinations.

#### e. Prolonged preoperative hospital stay

Prolonged preoperative hospital stay is frequently suggested as a patient characteristic associated with increased SSI risk. However, length of preoperative stay is likely a surrogate for severity of illness and co-morbid conditions requiring inpatient work-up and/or therapy before the operation.<sup>16,26,65,85,94,100,150,151</sup>

#### f. Preoperative nares colonization with *Staphylococcus aureus*

*S. aureus* is a frequent SSI isolate. This pathogen is carried in the nares of 20% to 30% of healthy humans.<sup>81</sup> It has been known for years that the development of SSI involving *S. aureus* is definitely associated with preoperative nares carriage of the organism in surgical patients.<sup>81</sup> A recent multivariate analysis demonstrated that such carriage was the most powerful independent risk factor for SSI following cardiothoracic operations.<sup>82</sup>

Mupirocin ointment is effective as a topical agent for eradicating *S. aureus* from the nares of colonized patients or healthcare workers. A recent report by Kluytmans and coworkers suggested that SSI risk was reduced in patients who had cardiothoracic operations when mupirocin was applied preoperatively to their nares, regardless of carrier status.<sup>152</sup> In this study, SSI rates for 752 mupirocin-treated patients were compared with those previously observed for an untreated group of 928 historical control patients, and the significant SSI rate reduction was attributed to the mupirocin treatment. Concerns have been raised regarding the comparability of the two patient groups.<sup>153</sup> Additionally, there is concern that mupirocin resistance may emerge, although this seems unlikely when treatment courses are brief.<sup>81</sup> A prospective, randomized clinical trial will be necessary to establish definitively that eradication of nasal carriage of *S. aureus* is an effective SSI prevention method in cardiac surgery. Such a trial has recently been completed on 3,909 patients in Iowa.<sup>83</sup> Five types of operations in two facilities were observed. Preliminary analysis showed a significant association between nasal carriage of *S. aureus* and subsequent SSI development. The effect of mupirocin on reducing SSI risk is yet to be determined.

#### g. Perioperative transfusion

It has been reported that perioperative transfusion of leukocyte-containing allogeneic blood components is an apparent risk factor for the development of postoperative bacterial infections, including SSI.<sup>106</sup> In three of five randomized trials conducted in patients undergoing elective colon resection for cancer, the risk of SSI was at least doubled in patients receiving blood transfusions.<sup>107-109</sup> However, on the basis of detailed epidemiologic reconsid-

TABLE 6

MECHANISM AND SPECTRUM OF ACTIVITY OF ANTISEPTIC AGENTS COMMONLY USED FOR PREOPERATIVE SKIN PREPARATION AND SURGICAL SCRUBS

Agent	Mechanism of Action	Gram-Positive Bacteria	Gram-Negative Bacteria	Mtb	Fungi	Virus	Rapidity of Action	Residual Activity	Toxicity	Uses
Alcohol	Denature proteins	E	E	G	G	G	Most rapid	None	Drying, volatile	SP, SS
Chlorhexidine	Disrupt cell membrane	E	G	P	F	G	Intermediate	E	Ototoxicity, keratitis	SP, SS
Iodine/Iodophors	Oxidation/substitution by free iodine	E	G	G	G	G	Intermediate	Minimal	Absorption from skin with possible toxicity, skin irritation	SP, SS
PCMX	Disrupt cell wall	G	F*	F	F	F	Intermediate	G	More data needed	SS
Triclosan	Disrupt cell wall	G	G	G	P	U	Intermediate	E	More data needed	SS

Abbreviations: E, excellent; F, fair; G, good; Mtb, *Mycobacterium tuberculosis*; P, poor; PCMX, para-chloro-meta-xenol; SP, skin preparation; SS, surgical scrubs; U, unknown. Data from Larson E.<sup>176</sup>

\* Fair, except for *Pseudomonas* spp.; activity improved by addition of chelating agent such as EDTA.

erations, as many as 12 confounding variables may have influenced the reported association, and any effect of transfusion on SSI risk may be either small or nonexistent.<sup>106</sup> Because of methodologic problems, including the timing of transfusion, and use of nonstandardized SSI definitions, interpretation of the available data is limited. A meta-analysis of published trials will probably be required for resolution of the controversy.<sup>154</sup> There is currently no scientific basis for withholding necessary blood products from surgical patients as a means of either incisional or organ/space SSI risk reduction.

## 2. Operative Characteristics: Preoperative Issues

### a. Preoperative antiseptic showering

A preoperative antiseptic shower or bath decreases skin microbial colony counts. In a study of >700 patients who received two preoperative antiseptic showers, chlorhexidine reduced bacterial colony counts ninefold ( $2.8 \times 10^2$  to 0.3), while povidone-iodine or triclocarban-medicated soap reduced colony counts by 1.3- and 1.9-fold, respectively.<sup>155</sup> Other studies corroborate these findings.<sup>156,157</sup> Chlorhexidine gluconate-containing products require several applications to attain maximum antimicrobial benefit, so repeated antiseptic showers are usually indicated.<sup>158</sup> Even though preoperative showers reduce the skin's microbial colony counts, they have not definitively been shown to reduce SSI rates.<sup>159-165</sup>

### b. Preoperative hair removal

Preoperative shaving of the surgical site the night before an operation is associated with a significantly higher SSI risk than either the use of depilatory agents or no hair removal.<sup>16,100,166-169</sup> In one study, SSI rates were 5.6% in patients who had hair removed by razor shave compared to a 0.6% rate among those who had hair removed by depilatory or who had no hair removed.<sup>166</sup> The increased SSI risk associated with shaving has been attributed to microscopic cuts in the skin that later serve as foci for bacterial multi-

plication. Shaving immediately before the operation compared to shaving within 24 hours preoperatively was associated with decreased SSI rates (3.1% vs 7.1%); if shaving was performed >24 hours prior to operation, the SSI rate exceeded 20%.<sup>166</sup> Clipping hair immediately before an operation also has been associated with a lower risk of SSI than shaving or clipping the night before an operation (SSI rates immediately before = 1.8% vs night before = 4.0%).<sup>170-173</sup> Although the use of depilatories has been associated with a lower SSI risk than shaving or clipping,<sup>166,167</sup> depilatories sometimes produce hypersensitivity reactions.<sup>166</sup> Other studies showed that preoperative hair removal by any means was associated with increased SSI rates and suggested that no hair be removed.<sup>100,174,175</sup>

### c. Patient skin preparation in the operating room

Several antiseptic agents are available for preoperative preparation of skin at the incision site (Table 6). The iodophors (e.g., povidone-iodine), alcohol-containing products, and chlorhexidine gluconate are the most commonly used agents. No studies have adequately assessed the comparative effects of these preoperative skin antiseptics on SSI risk in well-controlled, operation-specific studies.

Alcohol is defined by the FDA as having one of the following active ingredients: ethyl alcohol, 60% to 95% by volume in an aqueous solution, or isopropyl alcohol, 50% to 91.3% by volume in an aqueous solution.<sup>12</sup> Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic.<sup>176</sup> Aqueous 70% to 92% alcohol solutions have germicidal activity against bacteria, fungi, and viruses, but spores can be resistant.<sup>176,177</sup> One potential disadvantage of the use of alcohol in the operating room is its flammability.<sup>176-178</sup>

Both chlorhexidine gluconate and iodophors have broad spectra of antimicrobial activity.<sup>177,179-181</sup> In some comparisons of the two antiseptics when used as preoperative hand scrubs, chlorhexidine gluconate achieved greater reductions in skin microflora than did povidone-iodine and

also had greater residual activity after a single application.<sup>182-184</sup> Further, chlorhexidine gluconate is not inactivated by blood or serum proteins.<sup>176,179,185,186</sup> Iodophors may be inactivated by blood or serum proteins, but exert a bacteriostatic effect as long as they are present on the skin.<sup>178,179</sup>

Before the skin preparation of a patient is initiated, the skin should be free of gross contamination (i.e., dirt, soil, or any other debris).<sup>187</sup> The patient's skin is prepared by applying an antiseptic in concentric circles, beginning in the area of the proposed incision. The prepared area should be large enough to extend the incision or create new incisions or drain sites, if necessary.<sup>1,177,187</sup> The application of the skin preparation may need to be modified, depending on the condition of the skin (e.g., burns) or location of the incision site (e.g., face).

There are reports of modifications to the procedure for preoperative skin preparation which include: (1) removing or wiping off the skin preparation antiseptic agent after application, (2) using an antiseptic-impregnated adhesive drape, (3) merely painting the skin with an antiseptic in lieu of the skin preparation procedure described above, or (4) using a "clean" versus a "sterile" surgical skin preparation kit.<sup>188-191</sup> However, none of these modifications has been shown to represent an advantage.

#### **d. Preoperative hand/forearm antiseptics**

Members of the surgical team who have direct contact with the sterile operating field or sterile instruments or supplies used in the field wash their hands and forearms by performing a traditional procedure known as scrubbing (or the surgical scrub) immediately before donning sterile gowns and gloves. Ideally, the optimum antiseptic used for the scrub should have a broad spectrum of activity, be fast-acting, and have a persistent effect.<sup>1,192,193</sup> Antiseptic agents commercially available in the United States for this purpose contain alcohol, chlorhexidine, iodine/iodophors, para-chloro-meta-xyleneol, or triclosan (Table 6).<sup>176,177,179,194,195</sup> Alcohol is considered the gold standard for surgical hand preparation in several European countries.<sup>196-199</sup> Alcohol-containing products are used less frequently in the United States than in Europe, possibly because of concerns about flammability and skin irritation. Povidone-iodine and chlorhexidine gluconate are the current agents of choice for most U.S. surgical team members.<sup>177</sup> However, when 7.5% povidone-iodine or 4% chlorhexidine gluconate was compared to alcoholic chlorhexidine (60% isopropanol and 0.5% chlorhexidine gluconate in 70% isopropanol), alcoholic chlorhexidine was found to have greater residual antimicrobial activity.<sup>200,201</sup> No agent is ideal for every situation, and a major factor, aside from the efficacy of any product, is its acceptability by operating room personnel after repeated use. Unfortunately, most studies evaluating surgical scrub antiseptics have focused on measuring hand bacterial colony counts. No clinical trials have evaluated the impact of scrub agent choice on SSI risk.<sup>195,202-206</sup>

Factors other than the choice of antiseptic agent influence the effectiveness of the surgical scrub. Scrubbing technique, the duration of the scrub, the condition of the

hands, or the techniques used for drying and gloving are examples of such factors. Recent studies suggest that scrubbing for at least 2 minutes is as effective as the traditional 10-minute scrub in reducing hand bacterial colony counts,<sup>207-211</sup> but the optimum duration of scrubbing is not known. The first scrub of the day should include a thorough cleaning underneath fingernails (usually with a brush).<sup>180,194,212</sup> It is not clear that such cleaning is a necessary part of subsequent scrubs during the day. After performing the surgical scrub, hands should be kept up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows. Sterile towels should be used for drying the hands and forearms before the donning of a sterile gown and gloves.<sup>212</sup>

A surgical team member who wears artificial nails may have increased bacterial and fungal colonization of the hands despite performing an adequate hand scrub.<sup>212,213</sup> Hand carriage of gram-negative organisms has been shown to be greater among wearers of artificial nails than among non-wearers.<sup>213</sup> An outbreak of *Serratia marcescens* SSIs in cardiovascular surgery patients was found to be associated with a surgical nurse who wore artificial nails.<sup>214</sup> While the relationship between nail length and SSI risk is unknown, long nails—artificial or natural—may be associated with tears in surgical gloves.<sup>177,180,212</sup> The relationship between the wearing of nail polish or jewelry by surgical team members and SSI risk has not been adequately studied.<sup>194,212,215-217</sup>

#### **e. Management of infected or colonized surgical personnel**

Surgical personnel who have active infections or are colonized with certain microorganisms have been linked to outbreaks or clusters of SSIs.<sup>33,34,76,218-237</sup> Thus, it is important that healthcare organizations implement policies to prevent transmission of microorganisms from personnel to patients. These policies should address management of job-related illnesses, provision of postexposure prophylaxis after job-related exposures and, when necessary, exclusion of ill personnel from work or patient contact. While work exclusion policies should be enforceable and include a statement of authority to exclude ill personnel, they should also be designed to encourage personnel to report their illnesses and exposures and not penalize personnel with loss of wages, benefits, or job status.<sup>238</sup>

#### **f. Antimicrobial prophylaxis**

Surgical antimicrobial prophylaxis (AMP) refers to a very brief course of an antimicrobial agent initiated just before an operation begins.<sup>239-265</sup> AMP is not an attempt to sterilize tissues, but a critically timed adjunct used to reduce the microbial burden of intraoperative contamination to a level that cannot overwhelm host defenses. AMP does not pertain to prevention of SSI caused by postoperative contamination.<sup>265</sup> Intravenous infusion is the mode of AMP delivery used most often in modern surgical practice.<sup>20,26,242,266-281</sup> Essentially all confirmed AMP indications pertain to elective operations in which skin incisions are closed in the operating room.

**TABLE 7**  
SURGICAL WOUND CLASSIFICATION

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<i>Class I/Clean:</i> An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.
<i>Class II/Clean-Contaminated:</i> An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.
<i>Class III/Contaminated:</i> Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.
<i>Class IV/Dirty-Infected:</i> Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

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Garner JS<sup>1</sup> and Simmons BP<sup>2</sup>

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Four principles must be followed to maximize the benefits of AMP:

- Use an AMP agent for all operations or classes of operations in which its use has been shown to reduce SSI rates based on evidence from clinical trials or for those operations after which incisional or organ/space SSI would represent a catastrophe.<sup>266,268,269,282-284</sup>
- Use an AMP agent that is safe, inexpensive, and bactericidal with an in vitro spectrum that covers the most probable intraoperative contaminants for the operation.
- Time the infusion of the initial dose of antimicrobial agent so that a bactericidal concentration of the drug is established in serum and tissues by the time the skin is incised.<sup>285</sup>
- Maintain therapeutic levels of the antimicrobial agent in both serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room.<sup>179,266-268,282,284,286</sup> Because clotted blood is present in all surgical wounds, therapeutic serum levels of AMP agents are logically important in addition to therapeutic tissue levels. Fibrin-enmeshed bacteria may be resistant to phagocytosis or to contact with antimicrobial agents that diffuse from the wound space.

Table 4 summarizes typical SSI pathogens according to operation type and cites studies that establish AMP efficacy for these operations. A simple way to organize AMP indications is based on using the surgical wound classification scheme shown in Table 7, which employs descriptive case features to *postoperatively* grade the degree of intraoperative microbial contamination. A surgeon makes the decision to use AMP by anticipating *preoperatively* the surgical wound class for a given operation.

AMP is indicated for all operations that entail entry into a hollow viscus under controlled conditions. The most frequent SSI pathogens for such clean-contaminated operations are listed in Table 4. Certain clean-contaminated operations, such as elective colon resection, low anterior resection of the rectum, and abdominoperineal resection of the rectum, also require an additional preoperative protective maneuver called "preparation of the colon," to empty the

bowel of its contents and to reduce the levels of live microorganisms.<sup>200,239,256,268,284,287</sup> This maneuver includes the administration of enemas and cathartic agents followed by the oral administration of nonabsorbable antimicrobial agents in divided doses the day before the operation.<sup>200,288,289</sup>

AMP is sometimes indicated for operations that entail incisions through normal tissue and in which no viscus is entered and no inflammation or infection is encountered. Two well-recognized AMP indications for such clean operations are: (1) when any intravascular prosthetic material or a prosthetic joint will be inserted, and (2) for any operation in which an incisional or organ/space SSI would pose catastrophic risk. Examples are all cardiac operations, including cardiac pacemaker placement,<sup>290</sup> vascular operations involving prosthetic arterial graft placement at any site or the revascularization of the lower extremity, and most neurosurgical operations (Table 4). Some have advocated use of AMP during all operations on the breast.<sup>80,242,264</sup>

By definition, AMP is not indicated for an operation classified in Table 7 as contaminated or dirty. In such operations, patients are frequently receiving therapeutic antimicrobial agents perioperatively for established infections.

Cephalosporins are the most thoroughly studied AMP agents.<sup>284</sup> These drugs are effective against many gram-positive and gram-negative microorganisms. They also share the features of demonstrated safety, acceptable pharmacokinetics, and a reasonable cost per dose.<sup>242</sup> In particular, cefazolin is widely used and generally viewed as the AMP agent of first choice for clean operations.<sup>266</sup> If a patient is unable to receive a cephalosporin because of penicillin allergy, an alternative for gram-positive bacterial coverage is either clindamycin or vancomycin.

Cefazolin provides adequate coverage for many clean-contaminated operations,<sup>268,291</sup> but AMP for operations on the distal intestinal tract mandates use of an agent such as cefoxitin (or some other second-generation cephalosporin) that provides anaerobic coverage. If a patient cannot safely receive a cephalosporin because of allergy, a reasonable alternative for gram-negative cover-

**TABLE 8**

PARAMETERS FOR OPERATING ROOM VENTILATION, AMERICAN INSTITUTE OF ARCHITECTS, 1996

Temperature	68-73°F, depending on normal ambient temperatures
Relative humidity	30%-60%
Air movement	From "clean to less clean" areas
Air changes	Minimum 15 total air changes per hour Minimum 3 air changes of outdoor air per hour

American Institute of Architects.<sup>299</sup>

age is aztreonam. However, an agent such as clindamycin or metronidazole should also be included to ensure anaerobic coverage.

The aminoglycosides are seldom recommended as first choices for AMP, either as single drugs or as components of combination regimens.<sup>242,264</sup> References cited in Table 4 provide many details regarding AMP choices and dosages, antimicrobial spectra and properties, and other practical clinical information.

The routine use of vancomycin in AMP is not recommended for any kind of operation.<sup>242,266,283,292</sup> However, vancomycin may be the AMP agent of choice in certain clinical circumstances, such as when a cluster of MRSA mediastinitis or incisional SSI due to methicillin-resistant coagulase-negative staphylococci has been detected. A threshold has not been scientifically defined that can support the decision to use vancomycin in AMP. The decision should involve consideration of local frequencies of MRSA isolates, SSI rates for particular operations, review of infection prevention practices for compliance, and consultation between surgeons and infectious disease experts. An effective SSI surveillance program must be operational, with careful and timely culturing of SSI isolates to determine species and AMP agent susceptibilities.<sup>80</sup>

Agents most commonly used for AMP (i.e., cephalosporins) exhibit time-dependent bactericidal action. The therapeutic effects of such agents are probably maximized when their levels continuously exceed a threshold value best approximated by the minimal bactericidal concentration value observed for the target pathogens in vitro. When the duration of an operation is expected to exceed the time in which therapeutic levels of the AMP agent can be maintained, additional AMP agent should be infused. That time point for cefazolin is estimated as 3 to 4 hours. In general, the timing of a second (or third, etc.) dose of any AMP drug is estimated from three parameters: tissue levels achieved in normal patients by a standard therapeutic dose, the approximate serum half-life of the drug, and awareness of approximate MIC<sub>90</sub> values for anticipated SSI pathogens. References in Table 6 should be consulted for these details and important properties of antimicrobial agents used for AMP in various specialties.

Basic "rules of thumb" guide decisions about AMP dose sizes and timing. For example, it is believed that a full

therapeutic dose of cefazolin (1-2 g) should be given to adult patients no more than 30 minutes before the skin is incised.<sup>242,285</sup> There are a few exceptions to this basic guide. With respect to dosing, it has been demonstrated that larger doses of AMP agents are necessary to achieve optimum effect in morbidly obese patients.<sup>293</sup> With respect to timing, an exception occurs for patients undergoing cesarean section in whom AMP is indicated: the initial dose is administered immediately after the umbilical cord is clamped.<sup>266,272,273</sup> If vancomycin is used, an infusion period of approximately 1 hour is required for a typical dose. Clearly, the concept of "on-call" infusion of AMP is flawed simply because delays in transport or schedule changes can mean that suboptimal tissue and serum levels may be present when the operation starts.<sup>242,294</sup> Simple protocols of AMP timing and oversight responsibility should be locally designed to be practical and effective.

### 3. Operative characteristics: Intraoperative issues

#### a. Operating room environment

##### (1) Ventilation

Operating room air may contain microbial-laden dust, lint, skin squames, or respiratory droplets. The microbial level in operating room air is directly proportional to the number of people moving about in the room.<sup>295</sup> Therefore, efforts should be made to minimize personnel traffic during operations. Outbreaks of SSIs caused by group A beta-hemolytic streptococci have been traced to airborne transmission of the organism from colonized operating room personnel to patients.<sup>233,237,296,297</sup> In these outbreaks, the strain causing the outbreak was recovered from the air in the operating room.<sup>237,296</sup> It has been demonstrated that exercising and changing of clothing can lead to airborne dissemination of group A streptococci from vaginal or rectal carriage.<sup>233,234,237,297</sup>

Operating rooms should be maintained at positive pressure with respect to corridors and adjacent areas.<sup>298</sup> Positive pressure prevents airflow from less clean areas into more clean areas. All ventilation or air conditioning systems in hospitals, including those in operating rooms, should have two filter beds in series, with the efficiency of the first filter bed being  $\geq 30\%$  and that of the second filter bed being  $\geq 90\%$ .<sup>299</sup> Conventional operating room ventilation systems produce a minimum of about 15 air changes of filtered air per hour, three (20%) of which must be fresh air.<sup>299,300</sup> Air should be introduced at the ceiling and exhausted near the floor.<sup>300,301</sup> Detailed ventilation parameters for operating rooms have been published by the American Institute of Architects in collaboration with the U.S. Department of Health and Human Services (Table 8).<sup>299</sup>

Laminar airflow and use of UV radiation have been suggested as additional measures to reduce SSI risk for certain operations. Laminar airflow is designed to move particle-free air (called "ultraclean air") over the aseptic operating field at a uniform velocity (0.3 to 0.5  $\mu\text{m}/\text{sec}$ ), sweeping away particles in its path. Laminar airflow can be directed vertically or horizontally, and recirculated air is usually passed through a high efficiency particulate air (HEPA)

filter.<sup>302,303</sup> HEPA filters remove particles  $\geq 0.3\mu\text{m}$  in diameter with an efficiency of 99.97%.<sup>64,300,302,304</sup> Most of the studies examining the efficacy of ultraclean air involve only orthopedic operations.<sup>298,305-311</sup> Charnley and Eftaknan studied vertical laminar airflow systems and exhaust-ventilated clothing and found that their use decreased the SSI rate from 9% to 1%.<sup>305</sup> However, other variables (i.e., surgeon experience and surgical technique) changed at the same time as the type of ventilation, which may have confounded the associations. In a multicenter study examining 8,000 total hip and knee replacements, Lidwell et al. compared the effects of ultraclean air alone, antimicrobial prophylaxis alone, and ultraclean air in combination with antimicrobial prophylaxis on the rate of deep SSIs.<sup>307</sup> The SSI rate following operations in which ultraclean air alone was used decreased from 3.4% to 1.6%, whereas the rate for those who received only antimicrobial prophylaxis decreased from 3.4% to 0.8%. When both interventions were used in combination, the SSI rate decreased from 3.4% to 0.7%. These findings suggest that both ultraclean air and antimicrobial prophylaxis can reduce the incidence of SSI following orthopedic implant operations, but antimicrobial prophylaxis is more beneficial than ultraclean air. Intraoperative UV radiation has not been shown to decrease overall SSI risk.<sup>94,312</sup>

#### (2) Environmental surfaces

Environmental surfaces in U.S. operating rooms (e.g., tables, floors, walls, ceilings, lights) are rarely implicated as the sources of pathogens important in the development of SSIs. Nevertheless, it is important to perform routine cleaning of these surfaces to reestablish a clean environment after each operation.<sup>180,212,300,302</sup> There are no data to support routine disinfecting of environmental surfaces or equipment between operations in the absence of contamination or visible soiling. When visible soiling of surfaces or equipment occurs during an operation, an Environmental Protection Agency (EPA)-approved hospital disinfectant should be used to decontaminate the affected areas before the next operation.<sup>180,212,300-302,313-315</sup> This is in keeping with the Occupational Safety and Health Administration (OSHA) requirement that all equipment and environmental surfaces be cleaned and decontaminated after contact with blood or other potentially infectious materials.<sup>315</sup> Wet-vacuuming of the floor with an EPA-approved hospital disinfectant is performed routinely after the last operation of the day or night. Care should be taken to ensure that medical equipment left in the operating room be covered so that solutions used during cleaning and disinfecting do not contact sterile devices or equipment.<sup>316</sup> There are no data to support special cleaning procedures or closing of an operating room after a contaminated or dirty operation has been performed.<sup>300,301</sup>

Tacky mats placed outside the entrance to an operating room/suite have not been shown to reduce the number of organisms on shoes or stretcher wheels, nor do they reduce the risk of SSI.<sup>1,179,295,301</sup>

#### (3) Microbiologic sampling

Because there are no standardized parameters by which to compare microbial levels obtained from cultures

of ambient air or environmental surfaces in the operating room, routine microbiologic sampling cannot be justified. Such environmental sampling should only be performed as part of an epidemiologic investigation.

#### (4) Conventional sterilization of surgical instruments

Inadequate sterilization of surgical instruments has resulted in SSI outbreaks.<sup>302,317,318</sup> Surgical instruments can be sterilized by steam under pressure, dry heat, ethylene oxide, or other approved methods. The importance of routinely monitoring the quality of sterilization procedures has been established.<sup>1,180,212,299</sup> Microbial monitoring of steam autoclave performance is necessary and can be accomplished by use of a biological indicator.<sup>212,314,319</sup> Detailed recommendations for sterilization of surgical instruments have been published.<sup>212,314,320,321</sup>

#### (5) Flash sterilization of surgical instruments

The Association for the Advancement of Medical Instrumentation defines flash sterilization as “the process designated for the steam sterilization of patient care items for immediate use.”<sup>321</sup> During any operation, the need for emergency sterilization of equipment may arise (e.g., to reprocess an inadvertently dropped instrument). However, flash sterilization is not intended to be used for either reasons of convenience or as an alternative to purchasing additional instrument sets or to save time. Also, flash sterilization is not recommended for implantable devices(\*) because of the potential for serious infections.<sup>314,320,321</sup>

Flash sterilization is not recommended as a routine sterilization method because of the lack of timely biologic indicators to monitor performance, absence of protective packaging following sterilization, possibility for contamination of processed items during transportation to operating rooms, and use of minimal sterilization cycle parameters (i.e., time, temperature, pressure).<sup>319</sup> To address some of these concerns, many hospitals have placed equipment for flash sterilization in close proximity to operating rooms and new biologic indicators that provide results in 1 to 3 hours are now available for flash-sterilized items.<sup>322-325</sup> Nevertheless, flash sterilization should be restricted to its intended purpose until studies are performed that can demonstrate comparability with conventional sterilization methods regarding risk of SSI. Sterilization cycle parameters for flash sterilization are shown in Table 9.

#### b. Surgical attire and drapes

In this section the term *surgical attire* refers to scrub suits, caps/hoods, shoe covers, masks, gloves, and gowns. Although experimental data show that live microorganisms are shed from hair, exposed skin, and mucous membranes of operating room personnel,<sup>75,181,326-330</sup> few controlled clinical studies have evaluated the relationship between the use of surgical attire and SSI risk. Nevertheless, the use of barriers seems prudent to minimize a patient's exposure to the skin, mucous membranes, or hair of surgical team mem-

\* According to the FDA, an implantable device is a “device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more.”<sup>321</sup>

TABLE 9

PARAMETERS FOR FLASH STERILIZATION CYCLES, ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

Gravity-Displacement	Minimum Exposure Time and Temperature	
	Nonporous items	3 min at 132°C (270°F)
	Nonporous and porous items	10 min at 132°C (270°F)
Prevacuum	Minimum Exposure Time and Temperature	
	Nonporous items	3 min at 132°C (270°F)
	Nonporous and porous items	4 min at 132°C (270°F)

Association for the Advancement of Medical Instrumentation.<sup>321</sup>

bers, as well as to protect surgical team members from exposure to blood and bloodborne pathogens (e.g., human immunodeficiency virus and hepatitis viruses).

#### (1) Scrub suits

Surgical team members often wear a uniform called a "scrub suit" that consists of pants and a shirt. Policies for laundering, wearing, covering, and changing scrub suits vary greatly. Some policies restrict the laundering of scrub suits to the facility, while other facilities have policies that allow laundering by employees. There are no well-controlled studies evaluating scrub suit laundering as an SSI risk factor.<sup>331</sup> Some facilities have policies that restrict the wearing of scrub suits to the operating suite, while other facilities allow the wearing of cover gowns over scrub suits when personnel leave the suite. The Association of Operating Room Nurses recommends that scrub suits be changed after they become visibly soiled and that they be laundered only in an approved and monitored laundry facility.<sup>212</sup> Additionally, OSHA regulations require that "if a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible."<sup>315</sup>

#### (2) Masks

The wearing of surgical masks during operations to prevent potential microbial contamination of incisions is a longstanding surgical tradition. However, some studies have raised questions about the efficacy and cost-benefit of surgical masks in reducing SSI risk.<sup>328,332-338</sup> Nevertheless, wearing a mask can be beneficial since it protects the wearer's nose and mouth from inadvertent exposures (i.e., splashes) to blood and other body fluids. OSHA regulations require that masks in combination with protective eyewear, such as goggles or glasses with solid shields, or chin-length face shields be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated.<sup>315</sup> In addition, a respirator certified by the National Institute for Occupational Safety and Health with protection factor N95 or higher is required when the patient has or is suspected of having infectious tuberculosis.<sup>339</sup>

#### (3) Surgical caps/hoods and shoe covers

Surgical caps/hoods are inexpensive and reduce contamination of the surgical field by organisms shed from

the hair and scalp. SSI outbreaks have occasionally been traced to organisms isolated from the hair or scalp (*S. aureus* and group A *Streptococcus*),<sup>75,76</sup> even when caps were worn by personnel during the operation and in the operating suites.

The use of shoe covers has never been shown to decrease SSI risk or to decrease bacteria counts on the operating room floor.<sup>340,341</sup> Shoe covers may, however, protect surgical team members from exposure to blood and other body fluids during an operation. OSHA regulations require that surgical caps or hoods and shoe covers or boots be worn in situations when gross contamination can reasonably be anticipated (e.g., orthopedic operations, penetrating trauma cases).<sup>315</sup>

#### (4) Sterile gloves

Sterile gloves are put on after donning sterile gowns. A strong theoretical rationale supports the wearing of sterile gloves by all scrubbed members of the surgical team. Sterile gloves are worn to minimize transmission of microorganisms from the hands of team members to patients and to prevent contamination of team members' hands with patients' blood and body fluids. If the integrity of a glove is compromised (e.g., punctured), it should be changed as promptly as safety permits.<sup>315,342,343</sup> Wearing two pairs of gloves (double-gloving) has been shown to reduce hand contact with patients' blood and body fluids when compared to wearing only a single pair.<sup>344,345</sup>

#### (5) Gowns and drapes

Sterile surgical gowns and drapes are used to create a barrier between the surgical field and potential sources of bacteria. Gowns are worn by all scrubbed surgical team members and drapes are placed over the patient. There are limited data that can be used to understand the relationship of gown or drape characteristics with SSI risk. The wide variation in the products and study designs make interpretation of the literature difficult.<sup>329,346-350</sup>

Gowns and drapes are classified as disposable (single use) or reusable (multiple use). Regardless of the material used to manufacture gowns and drapes, these items should be impermeable to liquids and viruses.<sup>351,352</sup> In general, only gowns reinforced with films, coatings, or membranes appear to meet standards developed by the American Society for Testing and Materials.<sup>351-353</sup> However, such "liquid-proof" gowns may be uncomfortable because

they also inhibit heat loss and the evaporation of sweat from the wearer's body. These factors should be considered when selecting gowns.<sup>353,354</sup> A discussion of the role of gowns and drapes in preventing the transmission of blood-borne pathogens is beyond the scope of this document.<sup>355</sup>

### **c. Asepsis and surgical technique**

#### **(1) Asepsis**

Rigorous adherence to the principles of asepsis by all scrubbed personnel is the foundation of surgical site infection prevention. Others who work in close proximity to the sterile surgical field, such as anesthesia personnel who are separated from the field only by a drape barrier, also must abide by these principles. SSIs have occurred in which anesthesia personnel were implicated as the source of the pathogen.<sup>34,231,234,356-358</sup> Anesthesiologists and nurse anesthetists perform a variety of invasive procedures such as placement of intravascular devices and endotracheal tubes, and administration of intravenous drugs and solutions. Lack of adherence to the principles of asepsis during such procedures,<sup>359</sup> including use of common syringes<sup>360,361</sup> and contaminated infusion pumps,<sup>359,362-364</sup> and the assembly of equipment and solutions in advance of procedures,<sup>316,360</sup> have been associated with outbreaks of postoperative infections, including SSI. Recommendations for infection control practices in anesthesiology have been published.<sup>212,365-367</sup>

#### **(2) Surgical technique**

Excellent surgical technique is widely believed to reduce the risk of SSI.<sup>26,49,179,180,368,369</sup> Such techniques include maintaining effective hemostasis while preserving adequate blood supply, preventing hypothermia, gently handling tissues, avoiding inadvertent entries into a hollow viscus, removing devitalized (e.g., necrotic or charred) tissues, using drains and suture material appropriately, eradicating dead space, and appropriately managing the postoperative incision.

Any foreign body, including suture material, a prosthesis, or drain, may promote inflammation at the surgical site<sup>94</sup> and may increase the probability of SSI after otherwise benign levels of tissue contamination. Extensive research compares different types of suture material and their presumed relationships to SSI risk.<sup>370-379</sup> In general, monofilament sutures appear to have the lowest infection-promoting effects.<sup>3,94,179,180</sup>

A discussion of appropriate surgical drain use and details of drain placement exceed the scope of this document, but general points should be briefly noted. Drains placed through an operative incision increase incisional SSI risk.<sup>380</sup> Many authorities suggest placing drains through a separate incision distant from the operative incision.<sup>283,381</sup> It appears that SSI risk also decreases when closed suction drains are used rather than open drains.<sup>174</sup> Closed suction drains can effectively evacuate postoperative hematomas or seromas, but timing of drain removal is important. Bacterial colonization of initially sterile drain tracts increases with the duration of time the drain is left in place.<sup>382</sup>

Hypothermia in surgical patients, defined as a core body temperature below 36°C, may result from general anesthesia, exposure to cold, or intentional cooling such as

is done to protect the myocardium and central nervous system during cardiac operations.<sup>302,383,384</sup> In one study of patients undergoing colorectal operations, hypothermia was associated with an increased SSI risk.<sup>385</sup> Mild hypothermia appears to increase incisional SSI risk by causing vasoconstriction, decreased delivery of oxygen to the wound space, and subsequent impairment of function of phagocytic leukocytes (i.e., neutrophils).<sup>386-390</sup> In animal models, supplemental oxygen administration has been shown to reverse the dysfunction of phagocytes in fresh incisions.<sup>391</sup> In recent human experiments, controlled local heating of incisions with an electrically powered bandage has been shown to improve tissue oxygenation.<sup>392</sup> Randomized clinical trials are needed to establish that measures which improve wound space oxygenation can reduce SSI risk.

## **4. Operative Characteristics: Postoperative Issues**

### **a. Incision care**

The type of postoperative incision care is determined by whether the incision is closed primarily (i.e., the skin edges are re-approximated at the end of the operation), left open to be closed later, or left open to heal by second intention. When a surgical incision is closed primarily, as most are, the incision is usually covered with a sterile dressing for 24 to 48 hours.<sup>393,394</sup> Beyond 48 hours, it is unclear whether an incision must be covered by a dressing or whether showering or bathing is detrimental to healing. When a surgical incision is left open at the skin level for a few days before it is closed (delayed primary closure), a surgeon has determined that it is likely to be contaminated or that the patient's condition prevents primary closure (e.g., edema at the site). When such is the case, the incision is packed with a sterile dressing. When a surgical incision is left open to heal by second intention, it is also packed with sterile moist gauze and covered with a sterile dressing. The American College of Surgeons, CDC, and others have recommended using sterile gloves and equipment (sterile technique) when changing dressings on any type of surgical incision.<sup>180,395-397</sup>

### **b. Discharge planning**

In current practice, many patients are discharged very soon after their operation, before surgical incisions have fully healed.<sup>398</sup> The lack of optimum protocols for home incision care dictates that much of what is done at home by the patient, family, or home care agency practitioners must be individualized. The intent of discharge planning is to maintain integrity of the healing incision, educate the patient about the signs and symptoms of infection, and advise the patient about whom to contact to report any problems.

## **F. SSI SURVEILLANCE**

Surveillance of SSI with feedback of appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk.<sup>16,399,400</sup> A successful surveillance program includes the use of epidemiologically sound infection definitions (Tables 1 and 2) and effective

**TABLE 10**  
PHYSICAL STATUS CLASSIFICATION, AMERICAN SOCIETY OF ANESTHESIOLOGISTS\*

Code	Patient's Preoperative Physical Status
1	Normally healthy patient
2	Patient with mild systemic disease
3	Patient with severe systemic disease that is not incapacitating
4	Patient with an incapacitating systemic disease that is a constant threat to life
5	Moribund patient who is not expected to survive for 24 hours with or without operation

\* Reference 406.

Note: The above is the version of the ASA Physical Status Classification System that was current at the time of development of, and still is used in, the NNIS Risk Index. Meanwhile, the American Society of Anesthesiologists has revised their classification system; the most recent version is available at <http://www.asahq.org/proinfo/physicalstatus.html>.

surveillance methods, stratification of SSI rates according to risk factors associated with SSI development, and data feedback.<sup>25</sup>

### 1. SSI Risk Stratification

#### a. Concepts

Three categories of variables have proven to be reliable predictors of SSI risk: (1) those that estimate the intrinsic degree of microbial contamination of the surgical site, (2) those that measure the duration of an operation, and (3) those that serve as markers for host susceptibility.<sup>25</sup> A widely accepted scheme for classifying the degree of intrinsic microbial contamination of a surgical site was developed by the 1964 NAS/NRC Cooperative Research Study and modified in 1982 by CDC for use in SSI surveillance (Table 7).<sup>2,94</sup> In this scheme, a member of the surgical team classifies the patient's wound at the completion of the operation. Because of its ease of use and wide availability, the surgical wound classification has been used to predict SSI risk.<sup>16,94,126,401-405</sup> Some researchers have suggested that surgeons compare clean wound SSI rates with those of other surgeons.<sup>16,399</sup> However, two CDC efforts—the SENIC Project and the NNIS system—incorporated other predictor variables into SSI risk indices. These showed that even within the category of clean wounds, the SSI risk varied by risk category from 1.1% to 15.8% (SENIC) and from 1.0% to 5.4% (NNIS).<sup>125,126</sup> In addition, sometimes an incision is incorrectly classified by a surgical team member or not classified at all, calling into question the reliability of the classification. Therefore, reporting SSI rates stratified by wound class alone is not recommended.

Data on 10 variables collected in the SENIC Project were analyzed by using logistic regression modeling to develop a simple additive SSI risk index.<sup>125</sup> Four of these were found to be independently associated with SSI risk: (1) an abdominal operation, (2) an operation lasting >2 hours, (3) a surgical site with a wound classification of either contaminated or dirty/infected, and (4) an operation performed on a patient having  $\geq 3$  discharge diagnoses. Each of these equally weighted factors contributes a point when present, such that the risk index values range from 0 to 4. By using these factors, the SENIC index predicted SSI risk twice as well as the traditional wound classification scheme alone.

The NNIS risk index is operation-specific and applied to prospectively collected surveillance data. The index values range from 0 to 3 points and are defined by three independent and equally weighted variables. One point is scored for each of the following when present: (1) American Society of Anesthesiologists (ASA) Physical Status Classification of  $\geq 2$  (Table 10), (2) either contaminated or dirty/infected wound classification (Table 7), and (3) length of operation  $>T$  hours, where  $T$  is the approximate 75th percentile of the duration of the specific operation being performed.<sup>126</sup> The ASA class replaced discharge diagnoses of the SENIC risk index as a surrogate for the patient's underlying severity of illness (host susceptibility)<sup>406,407</sup> and has the advantage of being readily available in the chart during the patient's hospital stay. Unlike SENIC's constant 2-hour cut-point for duration of operation, the operation-specific cut-points used in the NNIS risk index increase its discriminatory power compared to the SENIC index.<sup>126</sup>

#### b. Issues

Adjustment for variables known to confound rate estimates is critical if valid comparisons of SSI rates are to be made between surgeons or hospitals.<sup>408</sup> Risk stratification, as described above, has proven useful for this purpose, but relies on the ability of surveillance personnel to find and record data consistently and correctly. For the three variables used in the NNIS risk index, only one study has focused on how accurately any of them are recorded. Cardo et al. found that surgical team members' accuracy in assessing wound classification for general and trauma surgery was 88% (95% CI: 82%-94%).<sup>409</sup> However, there are sufficient ambiguities in the wound class definitions themselves to warrant concern about the reproducibility of Cardo's results. The accuracy of recording the duration of operation (i.e., time from skin incision to skin closure) and the ASA class has not been studied. In an unpublished report from the NNIS system, there was evidence that overreporting of high ASA class existed in some hospitals. Further validation of the reliability of the recorded risk index variables is needed.

Additionally, the NNIS risk index does not adequately discriminate the SSI risk for all types of operations.<sup>27,410</sup> It seems likely that a combination of risk factors specific to patients undergoing an operation will be more predictive. A

few studies have been performed to develop procedure-specific risk indices<sup>218,411-414</sup> and research in this area continues within CDC's NNIS system.

## 2. SSI Surveillance Methods

SSI surveillance methods used in both the SENIC Project and the NNIS system were designed for monitoring inpatients at acute-care hospitals. Over the past decade, the shift from inpatient to outpatient surgical care (also called ambulatory or day surgery) has been dramatic. It has been estimated that 75% of all operations in the United States will be performed in outpatient settings by the year 2000.<sup>4</sup> While it may be appropriate to use common definitions of SSI for inpatients and outpatients,<sup>415</sup> the types of operations monitored, the risk factors assessed, and the case-finding methods used may differ. New predictor variables may emerge from analyses of SSIs among outpatient surgery patients, which may lead to different ways of estimating SSI risk in this population.

The choice of which operations to monitor should be made jointly by surgeons and infection control personnel. Most hospitals do not have the resources to monitor all surgical patients all the time, nor is it likely that the same intensity of surveillance is necessary for certain low-risk procedures. Instead, hospitals should target surveillance efforts toward high-risk procedures.<sup>416</sup>

### a. Inpatient SSI surveillance

Two methods, alone or together, have been used to identify inpatients with SSIs: (1) direct observation of the surgical site by the surgeon, trained nurse surveyor, or infection control personnel<sup>16,97,399,402,409,417-420</sup> and (2) indirect detection by infection control personnel through review of laboratory reports, patient records, and discussions with primary care providers.<sup>15,84,399,402,404,409,418,421-427</sup> The surgical literature suggests that direct observation of surgical sites is the most accurate method to detect SSIs, although sensitivity data are lacking.<sup>16,399,402,417,418</sup> Much of the SSI data reported in the infection control literature has been generated by indirect case-finding methods,<sup>125,126,422,425,426,428-430</sup> but some studies of direct methods also have been conducted.<sup>97,409</sup> Some studies use both methods of detection.<sup>84,409,424,427,431</sup> A study that focused solely on the sensitivity and specificity of SSIs detected by indirect methods found a sensitivity of 83.8% (95% CI: 75.7%-91.9%) and a specificity of 99.8% (95% CI: 99%-100%).<sup>409</sup> Another study showed that chart review triggered by a computer-generated report of antibiotic orders for post-cesarean section patients had a sensitivity of 89% for detecting endometritis.<sup>432</sup>

Indirect SSI detection can readily be performed by infection control personnel during surveillance rounds. The work includes gathering demographic, infection, surgical, and laboratory data on patients who have undergone operations of interest.<sup>433</sup> These data can be obtained from patients' medical records, including microbiology, histopathology, laboratory, and pharmacy data; radiology reports; and records from the operating room. Additionally, inpatient admissions, emergency room, and clinic visit

records are sources of data for those postdischarge surgical patients who are readmitted or seek follow-up care.

The optimum frequency of SSI case-finding by either method is unknown and varies from daily to  $\leq 3$  times per week, continuing until the patient is discharged from the hospital. Because duration of hospitalization is often very short, postdischarge SSI surveillance has become increasingly important to obtain accurate SSI rates (refer to "Postdischarge SSI Surveillance" section).

To calculate meaningful SSI rates, data must be collected on all patients undergoing the operations of interest (i.e., the population at risk). Because one of its purposes is to develop strategies for risk stratification, the NNIS system collects the following data on all surgical patients surveyed: operation date; NNIS operative procedure category;<sup>434</sup> surgeon identifier; patient identifier; age and sex; duration of operation; wound class; use of general anesthesia; ASA class; emergency; trauma; multiple procedures; endoscopic approach; and discharge date.<sup>433</sup> With the exception of discharge date, these data can be obtained manually from operating room logs or be electronically downloaded into surveillance software, thereby substantially reducing manual transcription and data entry errors.<sup>433</sup> Depending on the needs for risk-stratified SSI rates by personnel in infection control, surgery, and quality assurance, not all data elements may be pertinent for every type of operation. At minimum, however, variables found to be predictive of increased SSI risk should be collected (refer to "SSI Risk Stratification" section).

### b. Postdischarge SSI surveillance

Between 12% and 84% of SSIs are detected after patients are discharged from the hospital.<sup>98,337,402,428,435-454</sup> At least two studies have shown that most SSIs become evident within 21 days after operation.<sup>446,447</sup> Since the length of postoperative hospitalization continues to decrease, many SSIs may not be detected for several weeks after discharge and may not require readmission to the operating hospital. Dependence solely on inpatient case-finding will result in underestimates of SSI rates for some operations (e.g., coronary artery bypass graft) (CDC/NNIS system, unpublished data, 1998). Any comparison of SSI rates must take into account whether case-finding included SSIs detected after discharge. For comparisons to be valid, even in the same institution over time, the postdischarge surveillance methods must be the same.

Postdischarge surveillance methods have been used with varying degrees of success for different procedures and among hospitals and include (1) direct examination of patients' wounds during follow-up visits to either surgery clinics or physicians' offices,<sup>150,399,402,404,430,436,440,441,447,452,455</sup> (2) review of medical records of surgery clinic patients,<sup>404,430,439</sup> (3) patient surveys by mail or telephone,<sup>435,437,438,441,442,444,445,448,449,455-457</sup> or (4) surgeon surveys by mail or telephone.<sup>98,428,430,437-439,443,444,446,448,450,451,455</sup> One study found that patients have difficulty assessing their own wounds for infection (52% specificity, 26% positive predictive value),<sup>458</sup> suggesting that data obtained by patient questionnaire may inaccurately represent actual SSI rates.

Recently, Sands et al. performed a computerized search of three databases to determine which best identified SSIs: ambulatory encounter records for diagnostic, testing, and treatment codes; pharmacy records for specific antimicrobial prescriptions; and administrative records for rehospitalizations and emergency room visits.<sup>446</sup> This study found that pharmacy records indicating a patient had received antimicrobial agents commonly used to treat soft tissue infections had the highest sensitivity (50%) and positive predictive value (19%), although even this approach alone was not very effective.

As integrated health information systems expand, tracking surgical patients through the entire course of care may become more feasible, practical, and effective. At this time, no consensus exists on which postdischarge surveillance methods are the most sensitive, specific, and practical. Methods chosen will necessarily reflect the hospital's unique mix of operations, personnel resources, and data needs.

### c. Outpatient SSI surveillance

Both direct and indirect methods have been used to detect SSIs that complicate outpatient operations. One 8-year study of operations for hernia and varicose veins used home visits by district health nurses combined with a survey completed by the surgeon at the patient's 2-week postoperative clinic visit to identify SSIs.<sup>459</sup> While ascertainment was essentially 100%, this method is impractical for widespread implementation. High response rates have been obtained from questionnaires mailed to surgeons (72%–90%).<sup>443,444,446,455,459-461</sup> Response rates from telephone questionnaires administered to patients were more variable (38%,<sup>444</sup> 81%,<sup>457</sup> and 85%<sup>455</sup>), and response rates from questionnaires mailed to patients were quite low (15%<sup>455</sup> and 33%<sup>446</sup>). At this time, no single detection method can be recommended. Available resources and data needs determine which method(s) should be used and which operations should be monitored. Regardless of which detection method is used, it is recommended that the CDC NNIS definitions of SSI (Tables 1 and 2) be used without modification in the outpatient setting.

## G. GUIDELINE EVALUATION PROCESS

The value of the HICPAC guidelines is determined by those who use them. To help assess that value, HICPAC is developing an evaluation tool to learn how guidelines meet user expectations, and how and when these guidelines are disseminated and implemented.

## II. RECOMMENDATIONS FOR PREVENTION OF SURGICAL SITE INFECTION

### A. RATIONALE

The Guideline for Prevention of Surgical Site Infection, 1999, provides recommendations concerning reduction of surgical site infection risk. Each recommendation is categorized on the basis of existing scientific data, theoretical rationale, and applicability. However, the previous CDC system for categorizing recommendations has been modified slightly.

Category I recommendations, including IA and IB, are those recommendations that are viewed as effective by HICPAC and experts in the fields of surgery, infectious diseases, and infection control. Both Category IA and IB recommendations are applicable for, and should be adopted by, all healthcare facilities; IA and IB recommendations differ only in the strength of the supporting scientific evidence.

Category II recommendations are supported by less scientific data than Category I recommendations; such recommendations may be appropriate for addressing specific nosocomial problems or specific patient populations.

No recommendation is offered for some practices, either because there is a lack of consensus regarding their efficacy or because the available scientific evidence is insufficient to support their adoption. For such unresolved issues, practitioners should use judgement to determine a policy regarding these practices within their organization. Recommendations that are based on federal regulation are denoted with an asterisk.

### B. RANKINGS

*Category IA.* Strongly recommended for implementation and supported by well-designed experimental, clinical, or epidemiological studies.

*Category IB.* Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and strong theoretical rationale.

*Category II.* Suggested for implementation and supported by suggestive clinical or epidemiological studies or theoretical rationale.

*No recommendation; unresolved issue.* Practices for which insufficient evidence or no consensus regarding efficacy exists.

Practices required by federal regulation are denoted with an asterisk (\*).

## C. RECOMMENDATIONS

### 1. Preoperative

#### a. Preparation of the patient

1. Whenever possible, identify and treat all infections remote to the surgical site before elective operation and postpone elective operations on patients with remote site infections until the infection has resolved. *Category IA*

2. Do not remove hair preoperatively unless the hair at or around the incision site will interfere with the operation. *Category IA*

3. If hair is removed, remove immediately before the operation, preferably with electric clippers. *Category IA*

4. Adequately control serum blood glucose levels in all diabetic patients and particularly avoid hyperglycemia perioperatively. *Category IB*

5. Encourage tobacco cessation. At minimum, instruct patients to abstain for at least 30 days before elective operation from smoking cigarettes, cigars, pipes, or any other form of tobacco consumption (e.g., chewing/dipping). *Category IB*

6. Do not withhold necessary blood products from surgical patients as a means to prevent SSI. *Category IB*

7. Require patients to shower or bathe with an antiseptic agent on at least the night before the operative day. *Category IB*

8. Thoroughly wash and clean at and around the incision site to remove gross contamination before performing antiseptic skin preparation. *Category IB*

9. Use an appropriate antiseptic agent for skin preparation (Table 6). *Category IB*

10. Apply preoperative antiseptic skin preparation in concentric circles moving toward the periphery. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary. *Category II*

11. Keep preoperative hospital stay as short as possible while allowing for adequate preoperative preparation of the patient. *Category II*

12. No recommendation to taper or discontinue systemic steroid use (when medically permissible) before elective operation. *Unresolved issue*

13. No recommendation to enhance nutritional support for surgical patients solely as a means to prevent SSI. *Unresolved issue*

14. No recommendation to preoperatively apply mupirocin to nares to prevent SSI. *Unresolved issue*

15. No recommendation to provide measures that enhance wound space oxygenation to prevent SSI. *Unresolved issue*

#### **b. Hand/forearm antisepsis for surgical team members**

1. Keep nails short and do not wear artificial nails. *Category IB*

2. Perform a preoperative surgical scrub for at least 2 to 5 minutes using an appropriate antiseptic (Table 6). Scrub the hands and forearms up to the elbows. *Category IB*

3. After performing the surgical scrub, keep hands up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows. Dry hands with a sterile towel and don a sterile gown and gloves. *Category IB*

4. Clean underneath each fingernail prior to performing the first surgical scrub of the day. *Category II*

5. Do not wear hand or arm jewelry. *Category II*

6. No recommendation on wearing nail polish. *Unresolved Issue*

#### **c. Management of infected or colonized surgical personnel**

1. Educate and encourage surgical personnel who have signs and symptoms of a transmissible infectious illness to report conditions promptly to their supervisory and occupational health service personnel. *Category IB*

2. Develop well-defined policies concerning patient-care responsibilities when personnel have potentially transmissible infectious conditions. These policies should govern (a) personnel responsibility in using the health service and reporting illness, (b) work restrictions, and (c) clearance to resume work after an illness that required work restriction. The policies also should identify persons who have the authority to remove personnel from duty. *Category IB*

3. Obtain appropriate cultures from, and exclude

from duty, surgical personnel who have draining skin lesions until infection has been ruled out or personnel have received adequate therapy and infection has resolved. *Category IB*

4. Do not routinely exclude surgical personnel who are colonized with organisms such as *S. aureus* (nose, hands, or other body site) or group A *Streptococcus*, unless such personnel have been linked epidemiologically to dissemination of the organism in the healthcare setting. *Category IB*

#### **d. Antimicrobial prophylaxis**

1. Administer a prophylactic antimicrobial agent only when indicated, and select it based on its efficacy against the most common pathogens causing SSI for a specific operation (Table 4) and published recommendations.<sup>266,268,269,282-284</sup> *Category IA*

2. Administer by the intravenous route the initial dose of prophylactic antimicrobial agent, timed such that a bactericidal concentration of the drug is established in serum and tissues when the incision is made. Maintain therapeutic levels of the agent in serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room. *Category IA*

3. Before elective colorectal operations in addition to d2 above, mechanically prepare the colon by use of enemas and cathartic agents. Administer nonabsorbable oral antimicrobial agents in divided doses on the day before the operation. *Category IA*

4. For high-risk cesarean section, administer the prophylactic antimicrobial agent immediately after the umbilical cord is clamped. *Category IA*

5. Do not routinely use vancomycin for antimicrobial prophylaxis. *Category IB*

## **2. Intraoperative**

#### **a. Ventilation**

1. Maintain positive-pressure ventilation in the operating room with respect to the corridors and adjacent areas. *Category IB*

2. Maintain a minimum of 15 air changes per hour, of which at least 3 should be fresh air. *Category IB*

3. Filter all air, recirculated and fresh, through the appropriate filters per the American Institute of Architects' recommendations.<sup>299</sup> *Category IB*

4. Introduce all air at the ceiling, and exhaust near the floor. *Category IB*

5. Do not use UV radiation in the operating room to prevent SSI. *Category IB*

6. Keep operating room doors closed except as needed for passage of equipment, personnel, and the patient. *Category IB*

7. Consider performing orthopedic implant operations in operating rooms supplied with ultraclean air. *Category II*

8. Limit the number of personnel entering the operating room to necessary personnel. *Category II*

#### **b. Cleaning and disinfection of environmental surfaces**

1. When visible soiling or contamination with blood or other body fluids of surfaces or equipment occurs during an operation, use an EPA-approved hospital disinfectant to clean the affected areas before the next operation. *Category IB\**

2. Do not perform special cleaning or closing of operating rooms after contaminated or dirty operations. *Category IB*

3. Do not use tacky mats at the entrance to the operating room suite or individual operating rooms for infection control. *Category IB*

4. Wet vacuum the operating room floor after the last operation of the day or night with an EPA-approved hospital disinfectant. *Category II*

5. No recommendation on disinfecting environmental surfaces or equipment used in operating rooms between operations in the absence of visible soiling. *Unresolved issue*

#### **c. Microbiologic sampling**

1. Do not perform routine environmental sampling of the operating room. Perform microbiologic sampling of operating room environmental surfaces or air only as part of an epidemiologic investigation. *Category IB*

#### **d. Sterilization of surgical instruments**

1. Sterilize all surgical instruments according to published guidelines.<sup>212,299,314,321</sup> *Category IB*

2. Perform flash sterilization only for patient care items that will be used immediately (e.g., to reprocess an inadvertently dropped instrument). Do not use flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time. *Category IB*

#### **e. Surgical attire and drapes**

1. Wear a surgical mask that fully covers the mouth and nose when entering the operating room if an operation is about to begin or already under way, or if sterile instruments are exposed. Wear the mask throughout the operation. *Category IB\**

2. Wear a cap or hood to fully cover hair on the head and face when entering the operating room. *Category IB\**

3. Do not wear shoe covers for the prevention of SSI. *Category IB\**

4. Wear sterile gloves if a scrubbed surgical team member. Put on gloves after donning a sterile gown. *Category IB\**

5. Use surgical gowns and drapes that are effective barriers when wet (i.e., materials that resist liquid penetration). *Category IB*

6. Change scrub suits that are visibly soiled, contaminated, and/or penetrated by blood or other potentially infectious materials. *Category IB\**

7. No recommendations on how or where to launder scrub suits, on restricting use of scrub suits to the operating suite, or for covering scrub suits when out of the operating suite. *Unresolved issue*

#### **f. Asepsis and surgical technique**

1. Adhere to principles of asepsis when placing

intravascular devices (e.g., central venous catheters), spinal or epidural anesthesia catheters, or when dispensing and administering intravenous drugs. *Category IA*

2. Assemble sterile equipment and solutions immediately prior to use. *Category II*

3. Handle tissue gently, maintain effective hemostasis, minimize devitalized tissue and foreign bodies (i.e., sutures, charred tissues, necrotic debris), and eradicate dead space at the surgical site. *Category IB*

4. Use delayed primary skin closure or leave an incision open to heal by second intention if the surgeon considers the surgical site to be heavily contaminated (e.g., Class III and Class IV). *Category IB*

5. If drainage is necessary, use a closed suction drain. Place a drain through a separate incision distant from the operative incision. Remove the drain as soon as possible. *Category IB*

#### **3. Postoperative incision care**

a. Protect with a sterile dressing for 24 to 48 hours postoperatively an incision that has been closed primarily. *Category IB*

b. Wash hands before and after dressing changes and any contact with the surgical site. *Category IB*

c. When an incision dressing must be changed, use sterile technique. *Category II*

d. Educate the patient and family regarding proper incision care, symptoms of SSI, and the need to report such symptoms. *Category II*

e. No recommendation to cover an incision closed primarily beyond 48 hours, nor on the appropriate time to shower or bathe with an uncovered incision. *Unresolved issue*

#### **4. Surveillance**

a. Use CDC definitions of SSI (Table 1) without modification for identifying SSI among surgical inpatients and outpatients. *Category IB*

b. For inpatient case-finding (including readmissions), use direct prospective observation, indirect prospective detection, or a combination of both direct and indirect methods for the duration of the patient's hospitalization. *Category IB*

c. When postdischarge surveillance is performed for detecting SSI following certain operations (e.g., coronary artery bypass graft), use a method that accommodates available resources and data needs. *Category II*

d. For outpatient case-finding, use a method that accommodates available resources and data needs. *Category IB*

e. Assign the surgical wound classification upon completion of an operation. A surgical team member should make the assignment. *Category II*

f. For each patient undergoing an operation chosen for surveillance, record those variables shown to be associated with increased SSI risk (e.g., surgical wound class, ASA class, and duration of operation). *Category IB*

g. Periodically calculate operation-specific SSI rates

\* Federal regulation: OSHA.

stratified by variables shown to be associated with increased SSI risk (e.g., NNIS risk index). *Category IB*

h. Report appropriately stratified, operation-specific SSI rates to surgical team members. The optimum frequency and format for such rate computations will be determined by stratified case-load sizes (denominators) and the objectives of local, continuous quality improvement initiatives. *Category IB*

i. No recommendation to make available to the infection control committee coded surgeon-specific data. *Unresolved issue*

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